Applicant: Shin-ichi Funahashi et al. Attorney's Docket No.: 14875-081001 / C2-010PCT-

Serial No.: 09/831,846 Filed: May 15, 2001

Page : 6 of 8

REMARKS

Upon entry of the present amendment, claims 1-3 and 5-28 will be pending in the present application. Claim 4 is cancelled by the present submission, claims 12-28 are new, and claims 1-3 and 5-9 were withdrawn by the Examiner after restriction, leaving claims 10-28 currently under consideration. Claims 10 and 11 are presently amended. Support for the amendments and new claims can be found throughout the specification as filed, including at page 4, lines 14-17; page 4, line 29 through page 5, line 5; page 5, lines 26-34; page 6, lines 8-30; page 7, lines 7-15; page 10, lines 6-16; page 13, lines 24-31; page 15, lines 6-15; page 16, line 34 through page 17, line 24; page 13, line 35 through page 19, line 7; page 21, line 1 through page 24, line 36; page 32, lines 20-26; the sequence listing; and the claims as originally filed. No new matter has been added.

Applicants note that claim 10 has been allowed.

35 USC § 112, First Paragraph

Claims 4 and 11 were rejected under 35 USC § 112, first paragraph, because, according to the Examiner, "the specification, while being enabling for SEQ ID NO:2, does not reasonably provide enablement for any variant or functional equivalent of SEQ ID NO:2."

The enablement provision of the first paragraph of 35 USC § 112 requires that the specification describe how to make and use the invention as claimed. "The test of enablement is whether one reasonable skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." <u>United States v. Telectronics, Inc.</u>, 857 F.2d 778, 785 (Fed. Cir. 1988), cited in MPEP § 2164.01. Claim 4 has been cancelled, rendering the objection moot as to that claim. Claim 11 has been amended to limit the number of amino acids that can be added, deleted, or substituted. The term "functionally equivalent" in claim 11 has been deleted, and the claim has been further amended to specify that the protein variants bind a PDZ protein. This substantially limits the fragments and variants, both structurally and by function (since the variants are required to retain the binding function described). Any number of methods are known in the art to make the claimed

Applicant: Shin-ichi Funahashi et al. Attorney's Docket No.: 14875-081001 / C2-010PCT-

US

Serial No.: 09/831,846 Filed: May 15, 2001

Page : 7 of 8

variants (e.g., random or site-directed mutagenesis) and to test them for binding function (e.g., immunoprecipitation and two-hybrid systems) (see, e.g., page 4, line 29 through page 5, line 34). One of skill in the art would further know how to use these variants, e.g., to generate antibodies that bind to the intracellular or extracellular regions of the protein, *inter alia*. Such variants can also be used in screening methods, e.g., in yeast two-hybrid based methods, to screen for novel signal transducing substances, including neuropeptides (see, e.g., page 32, lines 31-33). Given the guidance supplied by the present specification (see, e.g., page 25, line 34 through page 26, line 17, and page 30, line 33 through page 31, line 10) and the general level of skill in the art, a skilled artisan would find little challenge in selecting a claimed variant, making the variant, and using it as described.

Applicants submit that claim 11 as amended is sufficiently enabled and request withdrawal of the rejection under 35 USC § 112, first paragraph.

35 USC § 112, Second Paragraph

Claims 4 and 11 are rejected under 35 USC § 112, second paragraph, as being indefinite. Specifically, the Examiner rejected claim 4 for failing to recite specific hybridizing conditions. Claim 4 has been cancelled, obviating the rejection thereof. Applicants have added new claim 14 that recites specific hybridizing conditions. Thus, this ground of rejection has been overcome.

Claim 11 was rejected for use of the term "functionally equivalent." Claim 11 has been amended to remove that term and instead to specify that the claimed variants bind a PDZ protein, thus specifying a particular function of the variants that correlates with a function of the protein of SEQ ID NO:2. Applicants submit that the claims as amended satisfy the requirements of 35 USC § 112, second paragraph.

For the foregoing reasons, Applicants submit that the claims as amended are patentable, and respectfully request rapid allowance of the same.

Applicant: Shin-ichi Funahashi et al.

Serial No.: 09/831,846 Filed: May 15, 2001

Page : 8 of 8

Attorney's Docket No.: 14875-081001 / C2-010PCT-

US

Applicants enclose as requested a verified translation of the Japanese priority application, Hei 10-331727. Also enclosed are a check for excess claim fees and a check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050, referencing attorney docket no. 14875-081001.

Date:

anjce/L. Kugler

Respectfully submitted,

Fish & Richardson P.C. 225 Franklin Street Boston, MA 02110-2804 Telephone: (617) 542-5070

Telephone: (617) 542-5070 Facsimile: (617) 542-8906

20776249.doc

.